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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,639	03/07/2002	Walter Schuler	4-100-8303C/C1D1	8447

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,639	SCHULER ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 11-28 are presented for examination.

Applicants' response filed August 19, 2005 has been received and entered.

Accordingly, the rejection made under 35 USC 103 as set forth in the previous Office action dated March 7, 2005; wherein the rejection pertains to preventing or treating noeintimal proliferation and thickening and/or restenosis and/or vascular occlusion for vascular injury with the said of 40-O-(2-hydroxy)ethyl-rapamycin with an effective amount of a second ingredient is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-28 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating neointimal proliferation and thickening and/or restenosis and/or vascular occlusion following vascular injury or manifestation of chronic rejection in a recipient of organ or tissue transplant or acute or chronic rejection in a recipient or organ or tissue xenograft transplant with the administration of only 40-O-(2-hydroxy)ethyl-rapamycin and a second agent , does not reasonably provide enablement for preventing neointimal proliferation and thickening and/or restenosis and/or vascular occlusion following vascular injury or manifestation of chronic rejection in a recipient of organ or tissue transplant or acute or chronic rejection in a recipient or organ or tissue xenograft transplant with the administration of only 40-O-(2-hydroxy)ethyl-rapamycin and a second agent . The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

Again, applicants' specification does not provide any examples showing the instant composition comprising 40-O-(2-hydroxy)ethyl-rapamycin and a second agent disclosed in claims 11 and 20 will, in fact, prevent neointimal proliferation and thickening and/or restenosis and/or vascular occlusion following vascular injury or

manifestation of chronic rejection in a recipient of organ or tissue transplant or acute or chronic rejection in a recipient or organ or tissue xenograft transplant especially in recipient not presently at risk of or predisposed to developing such a condition.

The rejection made under 35 USC 112, first paragraph is adhered to.

Claims 11-28 are not allowed.

To overcome this rejection, the application may wish to replace the word "preventing" with the word "inhibiting".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-28 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Cottens et al. (5,665,772 or AC of PTO-1449), of record, for reason of record as set forth in the previous Office action dated March 7, 2005 at page 7 as applied to claims 11-28.

Applicants' remarks regarding the Cottens et al. reference does not teach or is silent to the method of preventing or treating neointimal proliferation and thickening and/or restenosis and/or vascular occlusion following vascular injury with the administration of only 40-O-(2-hydroxy)ethyl-rapamycin and a second agent are

persuasive to the Examiner and the Examiner states in the opening response that this claim limitation that the rejection under 35 USC 103 is hereby withdrawn. But, to the methods of treating or preventing organ or tissue transplant rejection and preventing graft-versus-host disease with rapamycin derivatives including 40-O-(2-hydroxy)ethyl-rapamycin, and the rapamycin derivatives can be administrated together with other drugs. Note the other drugs are the same as applicants' in claims 11 and 20, such as ciclosporin, FK-506 or their immunosuppressive derivatives; corticosteroids; azathiprene; immunosuppressive monoclonal antibodies and other immunomodulatory compounds.

The rejection made under 35 USC 103 is adhered to.

Claims 11-28 are not allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
October 30, 2005